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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-------------------------------|--------------------------------|----------------------|---------------------|------------------|--|
| 10/586,768 | 07/20/2006 | Andreas Meudt | 2004DE302 | 7994 | |
| 38263 PROPAT, L.L. | 7590 11/05/200 C. | 8 | EXAMINER | | |
| 425-C SOUTH SHARON AMITY ROAD | | | MABRY, JOHN | | |
| CHARLOTTE, | E, NC 28211-2841 ART UNIT PAPE | | PAPER NUMBER | | |
| | | | 1625 | • | |
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| | | | MAIL DATE | DELIVERY MODE | |
| | | | 11/05/2008 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) MEUDT ET AL. 10/586,768 Office Action Summary Examiner Art Unit

| | | John Mabry, PhD | 1625 | | | | | |
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| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SH WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY THEVER IS LONGER, FROM THE MAILING DA STORY IN STATE AND THE MAILING DA THE MAILING THE MAILING THE THE MAILING THE THE MAILING THE THE MAILING THE THE THE THE THE THE THE THE | TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim Il apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this o D (35 U.S.C. § 133). | | | | | |
| Status | . , | | | | | | | |
| 2a)□ | Responsive to communication(s) filed on $\underline{05 \ Se}$ This action is FINAL . 2b) \boxtimes This . Since this application is in condition for allowan closed in accordance with the practice under \underline{E} . | action is non-final. ce except for formal matters, pro | | e merits is | | | | |
| Dispositi | ion of Claims | | | | | | | |
| 4)⊠ 5)□ 6)⊠ 7)□ | Claim(s) <u>1-12</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) <u>1-12</u> is/are rejected. Claim(s) is/are objected to. | | | | | | | |
| Applicati | ion Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | | |
| a) | Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau See the attached detailed Office action for a list of | have been received. have been received in Applicati ty documents have been receive (PCT Rule 17.2(a)). | on No ed in this National | Stage | | | | |
| | | | | | | | | |
| Attachmen | t(s) | | | | | | | |
| _ | o of References Cited (RTO 902) | 4) D Intonious Summons | (DTO 412) | | | | | |

 Notice of Traftsperson's Patent Drawing Review (PTO-948)
 Information Disclosure Statement(s) (FTO/SE/C6) Paper No(s)/Mail Date _____

 Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ______. 5) Notice of Informal Patent Application 6) Other: _____

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DETAILED ACTION

Request for Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 5, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no evidence/written description in the specification for R of Formulas II and III for the terms "substitution, akyl, alkenyl, alkynyl and cycloalkyl". Additionally, there are no examples or reduction to practice of said groups.

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According to the MPEP §2163 I. A. "the issue of a lock of adequate written description may arise even for an original claim when an aspect of the claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that eh applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in they are or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see I) (A), above), reduction to drawings (see I)(B), above), or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see I)(C), above). See Eli Lilly, 119 F.3d at 1568, 43, USPQ2d at 1406."

As discussed above the phrase "substitution, akyl, alkenyl, alkynyl and cycloalkyl" is not art recognized in the specification. According to the MPEP §2163.02 Standard for Determining Compliance With the Written Description Requirement,

"The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". In re Gosteli, 872, F.2d 1008 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention, an that the invention, in that context, is whatever is now claimed.

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The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375 217 USPQ 1089, 1096 (Fed. Cir. 1983))."

The methodology for determining adequacy of written description to convey that Applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement; (Federal Register/Vol 66. No. 4, Friday, January 5, 2001;11 Methodology for Determining Adequacy of Written Description (3.)).

Claim Coverage

The instant application claims a process for preparing a) nitriles of the formula II and b) isonitriles of the formula III.

Applicants' Reduction to Practice

According to the Specification at the time of filing, Examiner has concluded that Applicant was not in possession of the claimed invention.

Level of Skill and Knowledge in the Art

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The ordinary artisan is highly skilled, e.g. a masters or PhD in the chemical sciences. The level of skill in the art is high because of experimentation may be expansive and unpredictable.

According to the MPEP §2163 I. A. "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that eh applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the area or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see I) (A), above), reduction to drawings (see I)(B), above), or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see I)(C), above). See Eli Lilly, 119 F.3d at 1568, 43, USPQ2d at 1406."

As discussed above, the R groups being "akyl, alkenyl, alkynyl and cycloalkyl and the term substitution" is not defined or contained in the Specific and the art recognized definitions are shown to be inconsistent.

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According to the MPEP §2163.02 Standard for Determining Compliance with the Written Description Requirement,

"The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". In re Gosteli, 872, F.2d 1008 1012, 10 USPQ2d 1614, 1618 (Fed. Cir.1989), Under Vas-Cath. Inc. v. Mahurkar, 935 F.2d 1555. 1563-64, 19 USPQ2d 111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention, an that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375 217 USPQ 1089, 1096 (Fed. Cir. 1983)),"

Working Examples and Guidance Provided

The Specification does not demonstrate any support for R being anything

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chemical moiety other than phenyl, methylphenyl and methyl 3-phenylpropanoate. There are no working examples of claimed process wherein any "substitution, akyl, alkenyl, alkynyl and cycloalkyl" is used. The Specification does not even meet the minimum art recognized experimental standards. In the art, the claimed process of preparing only uses phenyl, methylphenyl and methyl 3-phenylpropanoate groups. However, there are no examples using art recognized where R is any chemical moiety other than phenyl, methylphenyl and methyl 3-phenylpropanoate in the instant applicant. There is no data is provided in the Specification that teaches the full claimed scope of how to make the products II and III.

State of the Art and Analysis of the Issues

The nature of the invention is the process of preparing compounds II and III where R is all aryl and heteroaryl groups (which is not defined in the Specification); the state of the prior art is not well developed and is highly unpredictable. There are no teachings of how to make the claimed compounds where R is "akyl, alkenyl, alkynyl and cycloalkyl with any substitution". This is merely an unsubstantiated assertion with no evidence to support. With the lack of examples and guidance as discussed above, one of ordinary skill in the art would reasonably have considered that at the time the application was filed, that the Applicant was not in possession of the claimed invention.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for Application/Control Number: 10/586,768 Page 8

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to John Mabry, PhD whose telephone number is (571)

270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's

primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor,

Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/ Examiner

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/Rita J. Desai/ Primary Examiner, Art Unit 1625